



Louis Stokes Cleveland Veterans Affairs Medical Center

APT Center-151 AW/APT T 216.791.3800
10701 East Boulevard F 216.707.6420
Cleveland, OH 44106 www.aptcenrer.org

POSITION ANNOUNCEMENT

Current Opening

Regulatory Affairs Specialist

The Advanced Platform Technology (APT) Center is seeking a Regulatory Affairs Specialist.

The APT Center develops technical interventions that serve the clinical needs of veterans with motor and sensory deficits and limb loss to provide clinicians and researchers with new tools for rehabilitation, treatment, and scientific inquiry that lead to enhanced independence and societal participation.

US CITIZENSHIP REQUIRED. Incumbent is required to develop and implement a cohesive regulatory documentation and monitoring system that meets regulatory guidelines, including the preparation and submission of documents to the FDA and Local IRBs. The system should address specific regulatory issues affecting research, development, and investigation of medical devices. The incumbent will collect, assemble, collate, interpret, and document all pertinent information needed for specific regulatory submissions. Ensure device design, manufacture, testing, deployment and evaluations are properly documented for regulatory reporting needs. Help plan, coordinate, and monitor clinical investigations of new devices; ensuring that research with human subjects is tracked, and that informed consent is obtained and documented.

Individuals meeting the qualifications and interested in the position should send their information to Suzana Iveljic, MBA, Director of Operations, Advanced Platform Technology Center at (sci4@case.edu) for consideration. Hardcopies can be sent to:

APT Center
Attn: Suzana C. Iveljic, MBA
Louis Stokes Veterans Affairs Medical Center
10701 East Blvd. Mail Stop 151 AW/APT
Cleveland, Ohio 44106
Fax: 216-707-6420
E-mail: sci4@case.edu